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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|--|------------------------------|----------------------------------|
| 10/770,727 | 02/02/2004 | Rong-Kun Chang | SHLI-035-002 | 1013 |
| 7590 | 01/05/2007 | Anna Ganelina Supernus Pharmaceuticals, Inc. 1550 East Gude Drive Rockville, MD 20850 | EXAMINER LEWIS, PATRICK T | ART UNIT 1623 PAPER NUMBER |
| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE | | |
| 3 MONTHS | 01/05/2007 | PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| | | |
|------------------------------|------------------------------|------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/770,727 | CHANG, RONG-KUN |
| | Examiner Patrick T. Lewis | Art Unit 1623 |

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-10 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
 5) Claim(s) ____ is/are allowed.
 6) Claim(s) 1-10 is/are rejected.
 7) Claim(s) ____ is/are objected to.
 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date 05072004.
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. ____.
 5) Notice of Informal Patent Application
 6) Other: ____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gidwani et al. US 6,828,334 (Gidwani).

Claims 1-10 are drawn to a pharmaceutical composition comprising a solubilizing agent selected from crystalline methylated α -, β -, and γ -cyclodextrin, or mixtures thereof, and a pharmaceutically active agent. Claim 2 limits the cyclodextrin. Claims 3 and 10 limit the active agent. Claims 4-9 limit the type of formulation (i.e. oral, parenteral, etc.)

Gidwani teaches a pharmaceutical composition containing fenofibrate in the form of an inclusion complex with methylated beta cyclodextrin (Example 6). The inclusion

complex can be administered as pharmaceutical formulations in form of tablets or in the form of granules inside a capsule (column 5, lines 20-45).

Gidwani differs from the instantly claimed invention in that 1) Gidwani is silent on the use of a crystalline cyclodextrin and 2) Gidwani does not teach liquid formulations.

Mere recitation of newly-discovered function or property (i.e., physical form), inherently possessed by things in prior art, does not cause claim drawn to those things to distinguish over prior art; Patent Office can require applicant to prove that subject matter shown to be in prior art does not possess characteristic relied on where it has reason to believe that functional limitation asserted to be critical for establishing novelty in claimed subject matter may be inherent characteristic of prior art; this burden of proof is applicable to product and process claims reasonably considered as possessing allegedly inherent characteristics. Patent and Trademark Office does not have facilities for examining and comparing applicant's various claimed crystalline forms with the prior art, and thus applicants have the burden of persuasion to make some comparison between materials in order to establish unexpected properties crystalline forms of methylated beta-cyclodextrin. Formulation of the composition of Gidwani into a cream or liquid is well within the purview of one of ordinary skill in the art.

Conclusion

4. Claims 1-10 are pending. Claims 1-10 are rejected. No claims are allowed.

Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 571-272-0655. The examiner can normally be reached on Monday - Friday 10 am to 3 pm (Maxi Flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Dr. Patrick T. Lewis
Primary Examiner
Art Unit 1623

ptl